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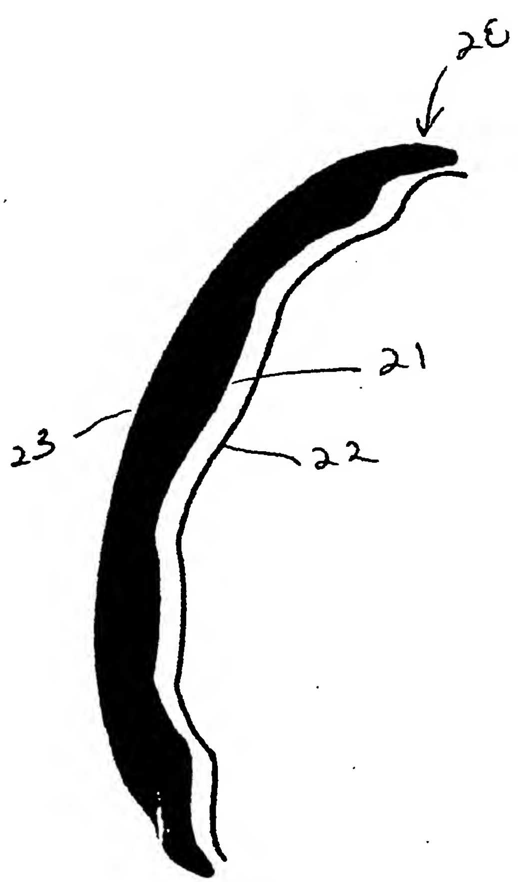
(54) Title: ROTATIONALLY STABILIZED CONTACT LENSES



(57) Abstract: The invention provides contact lenses that incorporate the wearer's corneal shape into the back surface of the lens to stabilize the orientation of the lens in relation to the eye.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

ROTATIONALLY STABILIZED CONTACT LENSES

Field of the Invention

The invention relates to contact lenses. In particular, the invention provides contact lenses that incorporate the wearer's corneal shape into the back surface of the lens to stabilize the orientation of the lens in relation to the eye.

Background of the Invention

It is known that correction of certain optical defects can be accomplished by imparting non-spherical corrective characteristics to one or more surfaces of a contact lens, such as cylindrical, bifocal, or multifocal characteristics. The use of contact lenses with these characteristics is problematic in that the lens must be maintained at a specific orientation while on the eye to be effective. However, the lens will rotate on the eye due to blinking as well as eyelid and tear fluid movement.

Lenses designed to maintain their on-eye orientation typically are of two general types. One type uses prism stabilization to maintain the lens orientation. Examples of prism stabilization methods include decentering of the lens' front surface relative to the back surface, prismatic balancing, thickening of the lower lens edge, supporting the lens on the lower eyelid, forming depressions or elevations on the lens' surface, and truncating the lens edge.

A second type, dynamically stabilized lenses, uses the movement of the eyelids to maintain lens orientation. Dynamic stabilization methods include reducing the thickness of the lens' outer surface at two symmetrically lying regions, thickening two outer regions in the horizontal center axis, and thinning, or slabbing off, top and bottom zones on the lens.

The known methods for maintaining lens orientation suffer from a number

of disadvantages including that the lenses incorporating the methods require specialized tooling for production and are uncomfortable to wear, and that the known methods are not highly effective. Thus, a need exists for a method of maintaining angular orientation that overcomes some of these disadvantages.

Brief Description of the Drawings

FIG. 1 illustrates a magnified, cross sectional view of a conventional soft contact lens on a cornea.

FIG. 2 illustrates a magnified, cross sectional view of a contact lens of the invention on a cornea.

Detailed Description of the Invention and Preferred Embodiments

It is a discovery of the invention that a rotationally stabilized contact lens may be obtained by incorporating the shape of the lens wearer's cornea onto the concave, or back, surface of the lens. The invention provides an effective method, and lenses incorporating that method, for on-eye lens stabilization that is produced without any specialized, off-axis tooling. Additionally, the invention provides a lens that is more comfortable to wear in comparison with conventional stabilized contact lenses.

In one embodiment, the invention provides a method for producing rotationally stabilized contact lenses comprising, consisting essentially of, and consisting of: a.) determining the shape of a cornea; and b.) forming a lens comprising, consisting essentially of, and consisting of a concave surface of a shape corresponding to the shape of the cornea.

In another embodiment, the invention provides a contact lens comprising, consisting essentially of, and consisting of a contact lens having a convex

surface and a concave surface, the concave surface comprising, consisting essentially of, and consisting of a shape corresponding to the shape of a cornea.

By "corresponding" is meant that a portion or all of the lens' concave surface is substantially superimposable onto the lens wearer's cornea. Preferably, in the lens of the invention, the central portion of the back surface corresponds to the cornea's shape. The portion of the cornea to which this central portion corresponds is that portion which the lens overlays while in use on the eye. In the preferred embodiment, a central portion of the lens is an area of about 8 to about 10 mm in diameter centered at the lens' center.

In the first step of the method of the invention, the shape of the cornea of the person who will wear the lens being produced is determined. The cornea's shape may be determined by any of the known methods including, without example, observation of the cornea with a corneal topographer or corneal video keratoscope. Any of a variety of known methods for acquiring corneal topographic data may be used. Suitable methods include, without limitation, use of the Moire technique, use of commercially available corneal topography measuring apparatuses, and the like and combinations thereof.

For purposes of forming a lens using the topographic data, the data is transformed mathematically into data on the elevation above and below the mean spherical surface of the cornea and the elevation data is then transformed into a grid pattern. The grid pattern may be of a rectilinear, polar concentric, or spiral format corresponding to the mechanism by which the back lens surface or lens mold or insert may be tooled using a computer numeric controlled lathe, mill, or bit addressable device. Alternatively, the surface may be formed by tooling or lathing using a programmable laser ablation device.

The lenses of the invention may be either hard or soft contact lenses. Preferably, the lenses are soft contact lenses. The lenses of the invention may have any of a variety of corrective optical characteristics incorporated onto the convex, or front, surface, the concave, or back surface, or both surfaces. For example, the lens may have any one or more of spheric, aspheric, bifocal, multifocal, prismatic, or cylindric corrections. The invention may find its greatest utility in lenses in which at least one of the corrective characteristics requires that the on-eye orientation of the lens with respect to the eye remains stable. In a preferred embodiment, the lens of the invention is a toric, soft contact lens meaning that the soft contact has a cylindrical optical surface, or power, to correct for the wearer's astigmatism.

In a more preferred embodiment, the lens is a lens customized for a particular lens wearer, such as a customized, topographically fitted contact lens. Such lenses may be provided by using ocular optical wavefront measurements carried out using, for example, the output of a crossed cylinder aberroscope, a device that measures ocular Modulation Transfer Function via point spread or line spread, or any similar device which measures, estimates, interpolates or calculates the ocular optical wavefront. The ocular optical wavefront information concerns the optical components of the eye, including the cornea, crystalline lens, system length, tilts, decentrations of the elements of the eye, asymmetrical irregularities, and asphericities.

The required changes in lens surface elevation or slope to achieve correction of the total ocular wavefront aberration may be implemented on the concave surface only, the convex surface only, or a combination thereof. The required surface elevation or slope changes will take into account the elevation changes required to fit and correct the irregularities in the corneal topography. In the case of a soft lens, because the soft lens wraps to the underlying shape of the cornea, the combined

elevation changes determined by the corneal topography and ocular wavefront aberration may be applied to the convex surface only, the concave surface only, or a combination thereof.

In the customized, topographically fitted lens preferred embodiment, conventional sphere-cylindrical prescriptive information also may be used in designing and forming the lens. This information includes the distance sphere, distance astigmatic cylinder power and axis, and the near vision power, if required. This information may be determined using conventional subjective refraction techniques. Alternatively, the sphere, cylinder and axis may be determined based on an analysis of the wavefront accomplished, for example, by reducing the Hartmann Shack wavefront data to Zernike coefficient terms, and using the relevant terms to derive the sphere, cylinder and axis information.

Although the lenses of the invention may be hard or soft lenses, preferably the material selected for forming the lenses of the invention is a material suitable for producing soft contact lenses. Suitable preferred materials for forming soft contact lenses using the method of the invention include, without limitation, silicone elastomers, silicone-containing macromers including, without limitation, those disclosed in United States Patent Nos. 5,371,147, 5,314,960, and 5,057,578 incorporated in their entireties herein by reference, hydrogels, silicone-containing hydrogels, and the like and combinations thereof. More preferably, the surface is a siloxane, or contains a siloxane functionality, including, without limitation, polydimethyl siloxane macromers, methacryloxypropyl polyalkyl siloxanes, and mixtures thereof, silicone hydrogel or a hydrogel, such as etafilcon A.

In the case in which the lens of the invention is a soft contact lens, initially, the elevation data is applied to the contact lens model in an unflexed state. The

contact lens back surface is ultimately shaped to correspond to the corneal surface taking into account lens flexure, or wrap, when the lens is placed on the eye. Typically, soft lenses are flatter than the cornea on which they are placed. Thus, both elevation and wrap must be considered when utilizing the original corneal topographic data to make a soft contact lens surface or mold insert.

The flexure transformed elevation data may be mapped onto a CNC grid pattern and used to make a lens or a mold tool surface. The resulting lens utilizing such information will be a lens that exhibits fluctuations in thickness on the grid pattern which may or may not be rotationally symmetrical about the center of the lens. When the manufactured soft lens wraps perfectly to the underlying cornea, the fluctuations in surface elevation will typically disappear. In this way, corneal irregularities may be neutralized and optical aberrations due to irregular corneal topography may likewise be substantially eliminated. To achieve any additional degree of optical correction, such as spherical or astigmatic focus, appropriate curvatures may be incorporated in the front surface, back surface, or both front and back surfaces of the lens.

For practical considerations, it is assumed that the ideal cornea is spherical. In such a case, the actual corneal elevations and their best spherical fit, in a least squares sense, are denoted by f(x) and g(x), respectively. The function g(x) is part of a sphere having radius R_1.

In general, the radius R_2 of the unflexed soft contact lens is spherical and is larger than that of the best spherical fit, g(x). Accordingly, the first step is to transform the corneal elevations f(x) into a larger scale for which the best spherical fit will have a radius equal to R_2. One approach in simplifying the transformation is to represent the function f(x) in polar coordinates as $f(\theta)$. Then, using a scale factor, $\alpha = R_2/R_1$, the scaled version of the corneal elevation may be expressed as:

$$f^{(1)}(\theta) = \alpha\, f(\theta) \qquad (1)$$

The scaled up corneal elevation $f^{(1)}(\theta)$ is scaled down so that the area covered by the soft lens corresponds to the area of the cornea. In a two dimensional case, this scaling down is obtained according to the following relationship:

$$f^{(2)}(\theta) = \alpha^{-1} f^{(1)}[(\theta - \pi/2)/\alpha + \pi/2] + R_2(1-1/\alpha) \qquad (2)$$

The mapping transformations given in Equations (1) and (2) are not restricted to the case in which the cornea and the back surface of the contact lens are spherical. Rather, the true corneal and lens curvatures, as measured by a videokeratoscope, may be used to calculate the scale parameter α as a ratio between the lens and the corneal radius of curvature. In the general case, the scale parameter will be a function of θ, i.e., $\alpha = R_2(\theta)/R_1(\theta) = \alpha(\theta)$.

The mapping transformation discussed above may be generalized to the case of three dimensional transformation. In such a case, the corneal elevations may be represented by a function, $f(\theta,\varphi)$, where θ and φ represent the azimuth and elevation angle, respectively. As discussed above, the original elevation data is scaled up from a radius of curvature $R_1(\theta,\varphi)$ onto a surface having a radius of curvature $R_2(\theta,\varphi)$ using the following transformation relationship:

$$f^{(1)}(\theta,\varphi) = \alpha\, f(\theta,\varphi) \qquad (3)$$

where $\alpha = R_2(\theta,\varphi)/R_1(\theta,\varphi)$.

To obtain a desired back surface of the soft contact lens, the function $f^{(1)}(\theta,\varphi)$ is scaled back down, as discussed above. However, in the three dimensional case, there are a number of options to choose from in performing the scaling operation such that the area is preserved. For example, if it is assumed that the deformation of the material is uniformly radial, the scaling may be performed by scaling the elevation angle only, leaving the original azimuth angle. This is expressed in the following relationship:

$$f^{(2)}(\theta,\varphi) = \alpha^{-1} f^{(1)} [\theta, (\alpha - \pi/2)/\alpha + \pi/2] + R_2 (1-1/\alpha) \qquad (4)$$

Referring to FIG. 1, a conventional soft contact lens 10 is shown. The disadvantage of using a conventional lens on a typical cornea, which has an irregular shape, is that the convex surface 11 of the lens assumes the irregular shape of the cornea. Assumption of this shape makes correction of aberrations of an order higher than the first difficult, thus, providing a less than optimal image. Additionally, when the convex surface assumes the shape of the cornea, increased lens movement on the eye may result.

In Fig. 2, a soft contact lens 20 of the invention is shown. Concave surface 21 of lens 20 has a shape corresponding to the shape of the cornea 22. By providing this corresponding shape, the lens is rotationally stabilized. Further, convex surface 23 of the lens will not assume the shape of the cornea making it possible to correct high order aberrations, if desired.

What is claimed is:

1. A method for producing rotationally stabilized contact lenses comprising the steps of: a.) determining the shape of a cornea; and b.) forming a lens comprising of a concave surface of a shape corresponding to the shape of the cornea.

2. The method of claim 1, wherein a central portion of the back surface corresponds to the shape of the cornea.

3. The method of claim 2, wherein the central portion is about 8 to about 10 mm in diameter.

4. The method of claim 1, wherein the determining step is carried out by using corneal topography

5. The method of claim 4, wherein the forming step comprises:

(i.) transforming topographic data into elevation data; and

(ii.) transforming, subsequently to substep (i.), the elevation data into a grid pattern corresponding to a mechanism for forming the back surface or a lens mold insert for use in forming the back surface.

6. The method of claim 5, further comprising (iii.) using the grid pattern to form the back surface or lens mold insert using a programmable laser ablation device.

7. A method for producing a rotationally stabilized soft contact lens comprising the steps of: a.) determining the shape of a cornea; and b.) forming a lens comprising of a concave surface of, a central portion of the concave surface corresponding to the shape of the cornea.

8. The method of claim 7, wherein the central portion is about 8 to about 10 mm in diameter.

9. The method of claim 7, wherein the determining step is carried out by using corneal topography and the forming step comprises:

(i.) transforming topographic data into elevation data; and

(ii.) transforming, subsequently to substep (i.), the elevation data into a grid pattern corresponding to a mechanism for forming the back surface or a lens mold insert for use in forming the back surface.

10. The method of claim 9, further comprising (iii.) using the grid pattern to form the back surface or lens mold insert using a programmable laser ablation device.

11. A method for producing a customized, topographically fitted, rotationally stabilized, soft contact lens comprising the steps of: a.) determining the shape of a cornea; and b.) forming a lens comprising of a concave surface of, a central portion of the concave surface corresponding to the shape of the cornea.

12. The method of claim 11, wherein the central portion is about 8 to about 10 mm in diameter.

13. The method of claim 11, wherein the determining step is carried out by using corneal topography and the forming step comprises:

(i.) transforming topographic data into elevation data; and

(ii.) transforming, subsequently to substep (i.), the elevation data into a grid pattern corresponding to a mechanism for forming the back surface or a lens mold insert for use in forming the back surface.

14. The method of claim 12, further comprising (iii.) using the grid pattern to form the back surface or lens mold insert using a programmable laser ablation device.

15. A contact lens produced by the method of claim 1.

16. A contact lens produced by the method of claim 7.

17. A contact lens produced by the method of claim 11.

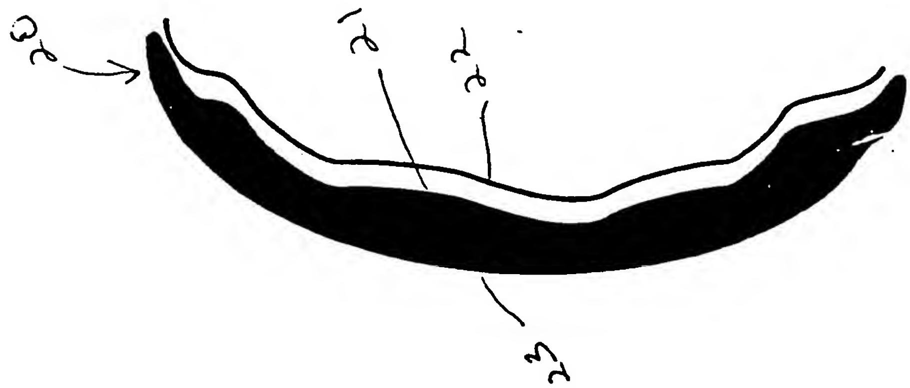

FIG. 2

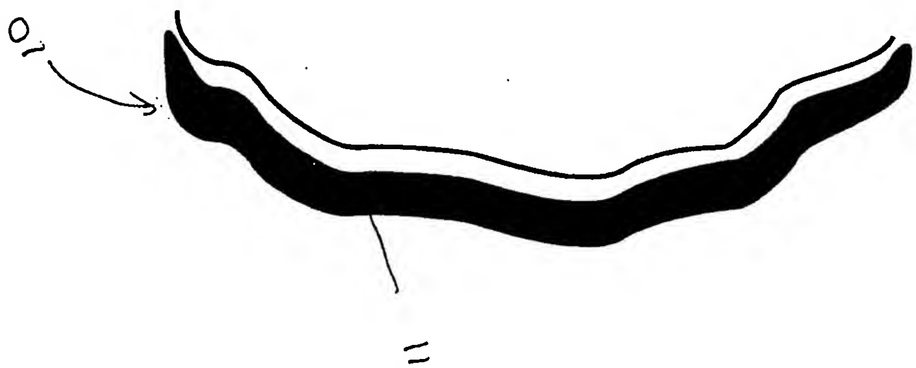

FIG. 1

INTERNATIONAL SEARCH REPORT

Intern. nal Application No
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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 G02C7/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 G02C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 953 098 A (LIEBERMAN DAVID M ET AL) 14 September 1999 (1999-09-14) column 5, line 7 - line 58 column 13, line 1 - line 11 column 15 ---	1,2,4-7, 9-11, 13-17
Y	WO 94 25887 A (BOSTON EYE TECHNOLOGY INC) 10 November 1994 (1994-11-10) page 7, line 27 -page 9, line 12 ---	1,2,4,7, 11
Y	WO 95 25981 A (INNOTECH INC) 28 September 1995 (1995-09-28) page 5, line 17 -page 9, line 10 page 16, line 31 - line 33 --- -/--	1,2,4,7, 11

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Date of the actual completion of the international search	Date of mailing of the international search report
10 January 2001	17/01/2001
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer CALLEWAERT, H

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Intern. nal Application No
PCT/US 00/28136

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 166 710 A (HERBRECHTSMEIER PETER ET AL) 24 November 1992 (1992-11-24) column 3, line 26 -column 6, line 64	1-17
A	US 4 194 815 A (TROMBLEY WAYNE E) 25 March 1980 (1980-03-25) claims	1-17

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter nal Application No
PCT/US 00/28136

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5953098 A	14-09-1999	US 5880809 A	09-03-1999
		AU 2348397 A	01-10-1997
		BR 9708072 A	27-07-1999
		CA 2248624 A	18-09-1997
		EP 0990191 A	05-04-2000
		NO 984246 A	16-11-1998
		PL 328802 A	15-02-1999
		WO 9734185 A	18-09-1997
WO 9425887 A	10-11-1994	US 5452031 A	19-09-1995
		AU 678481 B	29-05-1997
		AU 6767894 A	21-11-1994
		CA 2161890 A	10-11-1994
		EP 0724742 A	07-08-1996
		JP 9500973 T	28-01-1997
WO 9525981 A	28-09-1995	US 5598234 A	28-01-1997
		US 5517259 A	14-05-1996
		US 5528321 A	18-06-1996
		AU 689881 B	09-04-1998
		AU 2273295 A	09-10-1995
		CA 2181937 A	28-09-1995
		CN 1144565 A	05-03-1997
		EP 0746791 A	11-12-1996
		JP 9510800 T	28-10-1997
		US 5805266 A	08-09-1998
		US 5872613 A	16-02-1999
US 5166710 A	24-11-1992	AT 119689 T	15-03-1995
		AU 629725 B	08-10-1992
		AU 6934591 A	25-07-1991
		CA 2034719 A	25-07-1991
		DE 59104829 D	13-04-1995
		DK 439424 T	27-03-1995
		EP 0439424 A	31-07-1991
		ES 2069256 T	01-05-1995
		GR 3015347 T	30-06-1995
		HK 1000293 A	20-02-1998
		IE 65624 B	01-11-1995
		IL 96970 A	07-10-1994
		JP 3004741 B	31-01-2000
		JP 5034644 A	12-02-1993
		PT 96541 A	15-10-1991
US 4194815 A	25-03-1980	AU 521688 B	22-04-1982
		AU 4790979 A	03-01-1980
		CA 1116446 A	19-01-1982
		DE 2925194 A	03-01-1980
		FR 2430027 A	25-01-1980
		GB 2024450 A,B	09-01-1980
		JP 1199853 C	05-04-1984
		JP 55006386 A	17-01-1980
		JP 57004886 B	28-01-1982